PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

: Karl Tryggvason et al.

Serial No.

Unknown

Filed

Herewith

Title

PERFUSION APPARATUS AND METHODS

FOR PHARMACEUTICAL DELIVERY

Group Art Unit

Unknown

Examiner

Unknown

Attorney Docket

TRV 2 0010-1-1-3

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents Washington, D.C. 20231

Dear Sir:

In accordance with 37 C.F.R. §§ 1.56, 1.97, 1.98 and MPEP § 609, applicants submit the following Disclosure Statement concerning art of which the applicants are aware. A copy of PTO-1449 is enclosed herewith.

This Information Disclosure Statement is not intended to constitute an admission that any patent, publication or other information referred to herein or submitted herewith is "prior art" for this invention unless specifically designated as such.

In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

#2

Under § 1.98(a)(3), no concise explanation of relevance is required for information that is in the English language. Accordingly, the enclosed patents and other cited art require no further explanation.

U.S. Patents

5,328,470

5,336,178

5,338,662

5,382,229

5,521,291

Other Cited Art

Rosenfeld, M.A. et al. (1991) "Adenovirus-Mediated Transfer of a Recombinant α 1-Antirypsin Gene to the Lung Epithelium in Vivo" *Science* 252:431-434.

Tomita, N. et al. (1992) "Direct in vivo Gene Introduction Into Rat Kidney" Biochemical and Biophysical Research Communications 186:(1):129-134.

Davidson, B. L. et al. (1993) "A model system for in vivo gene transfer into the central nervous system using an adenoviral vector" *Nature Genetics* 4:27-34.

Englehardt, J.F. et al. (1993) "Direct gene transfer of human (FTR into human bronchial epithelia of xenografts with E1-deleted adenoviruses" Nature Genetics 4:27-34.

Isaka, Y. et al. (1993) "Glomerulosclerosis Induced by In Vivo Transfection of Transforming Growth Factor-β or Platelet-derived Growth Factor Gene into the Rat Kidney" *Journal of Clinical Investigation* 92:2597-2601.

Moullier et al., (1994) "Adenoviral-mediated gene transfer to renal tubular cells in

vivo" Kidney International 45:1220-1225.

Applicants submit that the U.S. patents and other cited art cited above for which no copies are provided were cited in a related application from which this application claims priority. Therefore copies are not required.

It is respectfully requested that the attached document(s) be considered and officially cited in examination of this application.

Respectfully submitted,

FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP

Richard J. Minnich Reg. No. 24,175 Brian G. Bembenick Reg. No. 41,463

1100 Superior Ave, 7th Floor Cleveland, OH 44114-2518

(216) 861-5582

CERTIFICATE OF EXPRESS MAILING

"Express Mail" Mailing Label Number <u>EL852683854US</u>
I hereby certify that this **Information Disclosure**Statement in connection with the above identified U.S. Patent Application is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

L:\ALB\DATA\2001\BGB\AUG01\TRV20010.IDS

Subst. Form PTO-1449		Atty. Docket No:TRV 20010-1-1-3			Serial No.: Unknown		
APPLICANT'S INFORMATION		Applicant:Karl Tryggvason et al.					
DISCLOSURE STATEMENT		Filing Date: Herewith			Group: Unknown		
U.S. PATENT DOCUMENTS							
Initia l*	Document No.	Date	Name	Class	Subcl	Filingn Date	
AA	5,327,470	7/1994					
AB	5,336,178	8/1994					
AC	5,338,662	8/1994					
AD	5,382,229	1/1995					
AE	5,521,291	5/1996					
OTHER ART							
AF	Rosenfeld, M.A. et al. (1991) "Adenovirus-Mediated Transfer of a Recombinant α1-Antirypsin Gene to the Lung Epithelium in Vivo" Science 252:431-434.						
AG	Tomita, N. et al. (1992) "Direct in vivo Gene Introduction Into Rat Kidney" Biochemical and Biophysical Research Communications 186:(1):129-134.						
АН	Davidson, B. L. et al. (1993) "A model system for in vivo gene transfer into the central nervous system using an adenoviral vector" Nature Genetics 4:27-34.						
AI	Englehardt, J.F. et al. (1993) "Direct gene transfer of human (FTR into human bronchial epithelia of xenografts with E1-deleted adenoviruses" Nature Genetics 4:27-34.						
AJ	Isaka, Y. et al. (1993) "Glomerulosclerosis Induced by In Vivo Tranfection of Transforming Growth Factor-β or Platelet-derived Growth Factor Gene into the Rat Kidney" Journal of Clinical Investigation 92:2597-2601.						
AK	Moullier et al., (1994) "Adenoviral-mediated gene transfer to renal tubular cells in vivo" <i>Kidney International</i> 45:1220-1225.						
Examiner:				Date	Date Considered:		

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication to applicant.